



July 8, 2003

Jo Anne B. Barnhart
Commission of Social Security
P.O. Box 1770
Baltimore, Maryland 21235-7703

Dear Commissioner Barnhart:

Thank you for the opportunity to comment in advance of the potential revisions you have announced for the rules used to evaluate immune system disorders of individuals who seek disability benefits and insurance payments under Titles II and XVI of the Social Security Act. I am submitting these comments on behalf of a working group of physician members of the HIV Medicine Association. The HIV Medicine Association (HIVMA) is a national organization representing more than 2600 HIV physicians. HIVMA represents the interests of patients by promoting quality in HIV care by advocating for policies that ensure a comprehensive and humane response to the AIDS pandemic informed by science and social justice.

The working group formed to respond to the Social Security disability listings for HIV/AIDS is comprised of distinguished physicians who have longstanding involvement in clinical practice and research devoted to HIV Medicine. The membership is as follows: Judith Aberg, MD, St. Louis, MO; Sam Bozzette, MD, PhD, San Diego, CA; Richard Elion, MD, Washington, DC; Stephen Becker, MD, San Francisco, CA; Dan Kuritzkes, MD, Boston, MA; Andrew Pavia, MD, Salt Lake City, UT; Mobeen Rathore, MD, Jacksonville, FL; Anita Vaughn, MD, Newark, NJ; and Bruce Williams, MD, Albuquerque, NM. Doctors Rathore and Pavia are pediatric infectious diseases specialists. Members of this work group and other members of HIVMA would be happy to serve as an ongoing resource to you and other staff members of the Social Security Administration. Our perspective and contributions to this issue are necessarily limited by our role as treating physicians of HIV patients who are frequently called upon to document medical conditions utilized in disability claims. We encourage you to review closely the comments of other important constituencies that have valuable expertise to offer to this process including attorneys with experience in adjudicating HIV-related disability claims, as well as comments that may be offered from HIV patients and patient advocates.

There is clearly value in ensuring that the disability listings related to HIV disease reflect the current state of knowledge regarding HIV disease, its manifestations and treatment options. However, modifications of the listings represents a very serious enterprise given the potential impact of any changes on the eligibility of current and future Social Security disability beneficiaries with HIV disease on health care access under Medicare and Medicaid. We understand that issues related to the linkage of disability cash assistance and Medicaid and

Medicare eligibility are beyond the purview of this proposed rulemaking. Nevertheless, our obligation as physicians treating patients with HIV disease requires us to raise concerns about this link that may translate into many disability beneficiaries with HIV disease losing access to cash assistance and Medicaid or Medicare precisely because health care provided under those programs has resulted in a positive change in health status that no longer meets the SSA disability standard.

This is an issue of enormous importance because public insurance is the largest payer of HIV care and disability status provides crucial access to public programs. While we clearly acknowledge and embrace the governmental and public interest inherent in ensuring that persons with HIV/AIDS legitimately qualify for disability cash assistance based on their inability to engage in gainful employment, we also have grave concerns about the potential loss of health benefits under Medicaid and Medicare. Access to health care under these programs is likely the primary reason for health improvement in beneficiaries who are responsive to HIV treatment. There is also little doubt that the health status of persons with HIV disease will deteriorate if access to care and prescription drugs ceases. We also understand that this predicament is not unique to persons with HIV disease, but is pertinent to many Social Security beneficiaries who have chronic, disabling conditions for which there are available treatments. A number of policy changes that would serve to de-link eligibility for disability cash assistance with Medicaid and Medicare eligibility would ameliorate this situation. We offer these suggestions for the consideration of the Social Security Administration and the Bush Administration:

- Allow SSI and SSDI beneficiaries who are denied recertification based on health improvement to continue to receive Medicaid and/or Medicare benefits if no other health coverage options are available to them.
- Include beneficiaries eliminated from the disability rolls because of health improvement as eligible populations for the Ticket to Work and Work Incentive Improvement Act state Medicaid options.
- Allow more flexibility for SSI and SSDI beneficiaries to move on and off the program if their medical condition renders them periodically disabled, as is the case for many individuals with HIV disease and other chronic illnesses. The duration of disability coverage should be made more flexible to reflect actual clinical conditions. It is reasonable, for example, to grant six months of disability coverage during convalescence from *Pneumocystis Carinii* Pneumonia (PCP), with extensions as clinically indicated. Medicaid and/or Medicare coverage should continue without disruption.
- Implement a phased re-entry for persons determined ineligible for continuing disability assistance in which support continues during early re-employment to ensure that the employment is tolerated and does not result in relapse.
- Support the enactment of the Early Treatment for HIV Act (ETHA) which would offer states the option of providing Medicaid coverage to low-income individuals with HIV disease with no access to private health insurance who are not yet disabled by AIDS.

Overview of Listings

Much has changed in HIV medicine since 1993 when these disability listings were last updated. While HIV infection remains incurable, treatment advances have contributed to dramatic reductions in HIV-related morbidity and mortality. However, according to the Centers for Disease Control and Prevention, at least one-quarter of individuals who are infected with HIV do not know their status.¹ A significant number of persons who know about their HIV infection are not in care for a variety of reasons. Too many individuals with HIV disease still find out about their HIV infection after being hospitalized because of an HIV-related opportunistic infection. There are also many individuals who do not respond to treatment for a variety of reasons including resistance to therapeutic drugs and the presence of co-morbidities such as serious and persistent mental illness which compromise their functioning and their ability to fully benefit from health care services.^{2 3} All of these groups are vulnerable to the deadly and disabling progression of HIV disease.

It is important for the introduction to the listings to acknowledge that not all individuals with HIV disease have access to treatment and that not all individuals in HIV care benefit from treatment in ways that fully restore their functioning. Moreover, disabling mental illness both related and independent of HIV disease itself is so frequently a diagnosis of our patients that we believe this issue should be highlighted in the listings. Inquiry into mental health and the ramifications of mental disorders for HIV disease and HIV-related disability claims is important.

HIV therapy is often life saving, but it can also be disabling. Social Security's process distinguishes between symptoms and side effects—granting more weight to symptoms, but the distinction is not always clear. Medication side effects can potentiate the underlying disease. For example, HIV-related neuropathy may be exacerbated by the use of key antiretroviral agents. Neuropathy can be a very disabling condition. Moreover, pain medications, including narcotics, utilized to treat neuropathy can impair functioning, and render the patient unable to work. We suggest that Section 14.00 be modified to reflect a more detailed discussion of the impact of medications on patients with HIV disease. It is also important to acknowledge that treatment is not always effective and that the efficacy of an antiretroviral regimen may be time-limited for a given individual. Consequently, individuals may experience a deterioration of their health and functioning despite their adherence to a standard treatment regimen.

We support the maintenance of the stand-alone listings for HIV/AIDS for the purpose of establishing presumptive eligibility, but we also realize that many claims may warrant an individualized functional assessment to determine disability. HIV medicine has become an

¹ Fleming P, et al. HIV Prevalence in the United States, 2000. [Abstract] In: Program and Abstracts of the 9th Conference on Retroviruses and Opportunistic Infections, Seattle, Washington, February 24-28, 2002. Alexandria, Virginia: Foundation for Retrovirology and Human Health.

² Little, SJ et al. Antiretroviral-Drug Resistance Among Patients Recently Infected with HIV. N Engl J Med 2002;347(6):385-394.

³ Greenberg ML, et al. Baseline and On-treatment Susceptibility to Enfuvirtide Seen in TORO 1 and TORO 2 to 24 Weeks. Oral abstract presented at the 10th Conference on Retroviruses and Opportunistic Infections. Available online at www.retroconference.org/2003/Abstract/Abstract.aspx?AbstractID=1687.

increasingly complex and specialized area of medicine. While it may not be possible to have each claim for HIV-related disability evaluated by a medical expert with direct experience treating patients with HIV disease, we believe it is essential that an experienced HIV physician be involved in evaluating disputed claims. (See 14.00 Section 8. Functional Criteria for more detail).

We offer the following recommendations regarding the introduction to the listings.

14.00 Section 3. Documentation of HIV Infection

This section should be updated to reflect advances in medical technology and knowledge.

Additionally, we recommend:

- Requiring diagnosis of HIV either through antibody or antigen testing, which is the current medical standard and eliminating 3 b. other acceptable documentation of HIV infection.

14.00 Section 7. Effect of Treatment

Significant advancements have been made in the treatment of HIV disease; however, the complexity and intensity of these regimens potentiate underlying diseases such as neuropathy. Furthermore, the toxicities of therapy for HIV disease create a situation where treatment for the disease itself, while lifesaving, is often disabling. For these reasons, this section should reflect the fact that symptoms of HIV disease and side effects from its treatment are equally disabling and often indistinguishable.

14.00 Section 6. Evaluation

The prevalence of mental health disorders, e.g., major depression, among people with HIV disease is disproportionately high.⁴⁵⁶ Regardless of whether the mental illness is a manifestation of HIV disease or a pre-existing condition, mental illnesses have a major effect on a patient's ability to function and, in particular, access medical care. The high prevalence and negative impact of mental illnesses on treatment for HIV disease should be reflected in this section and taken into consideration during evaluations of HIV disability cases.

⁴ Asch SM, et al. Underdiagnosis of Depression in HIV. J Gen Intern Med 2003;18(6):450-460.

⁵ Ichkovis JR, et al. Mortality, CD4 Cell Count Decline and Depressive Symptoms Among HIV-Seropositive Women, Longitudinal Analysis from the HIV Epidemiology Research Study. JAMA 2001; 285(11): 1466-1474.

⁶ Angelino AF, Treisman GJ. Management of Psychiatric Disorders in Patients Infected with Human Immunodeficiency Virus. Clin Infect Dis 2001; 33:847-856.

14.00 Section 8. Functional Criteria

Medical advances in the treatment of HIV disease also demand increased knowledge and expertise on the part of physicians treating people with HIV disease. With this in mind, we strongly recommend that medical examiners reviewing HIV disability cases are familiar with HIV medicine. Furthermore, disputes that arise regarding functional assessments should be resolved by a physician who meets the generally agreed upon criteria for identifying HIV expertise, i.e., a physician who in the immediately preceding 24 months has provided continuous and direct medical care to a minimum of 20 patients who are infected with HIV and in the same 24 month period has successfully completed a minimum of 30 hours of Category 1 continuing medical education in the diagnosis and treatment of HIV-infected patients.⁷⁸⁹

We offer the following comments for the disability listings for HIV infection for adults.

14.08 Human immunodeficiency virus (HIV) infection

Stand-Alone Listings

As you know, the stand-alone listings were developed to provide a shortcut to establishing disability for people with AIDS because prior to their development people with AIDS were expiring before they were able to access benefits that would have prolonged their lives. Even with the advances that have been made in the treatment of HIV disease, a significant number of patients are not diagnosed until they have progressed, or are near progression, to AIDS.¹⁰ For these patients, it is vital that the stand-alone listings are maintained so that they are able to access life-saving benefits. We strongly recommend maintaining all of the current stand-alone listings A-L with the modifications and additions noted below.

General Comment

- For all of the listings, we recommend the addition of a category similar to 14.08 H.2 that recognizes that new or different manifestations of the conditions emerge. For listings A through G (bacterial infections, fungal infections, protozoan or helminthic infections, viral infections, malignant neoplasms, and hematologic abnormalities), we recommend the following language be added “an infection or condition that is systemic or disseminated.”

⁷ Landon BE, et al. Specialty Training and Specialization Among Physicians Who Treat HIV/AIDS in the United States. *J Gen Intern Med* 2002; 17(1): 12-22.

⁸ Stone VE, et al. Relation of Physician Specialty and HIV/AIDS Experience to Choice of Guideline-Recommended Antiretroviral Therapy. *J Gen Intern Med* 2001; 16:360-368.

⁹ See also attached list of definitions used by states, policy makers and other health care organizations for identifying HIV-experienced providers. Also available online at www.hivma.org/HIV/HIVnet_ProDef.htm.

¹⁰ Neil JJ, Fleming PL. Frequency and Predictors of Late HIV Diagnosis in the United States, 1994 through 1999. In: Final Program and Abstracts of the 9th Conference on Retroviruses and Opportunistic Infections, Seattle, Washington, February 24-28, 2002. Alexandria, Virginia: Foundation for Retrovirology and Human Health.

14.08 A. Bacterial infections

- Modify 1. Mycobacterial infection at site other than lungs, skin, or cervical or hilar lymph nodes to include pulmonary tuberculosis and eliminate the requirement that it is “resistant to treatment”
- Add “6. Rhodococcus”

14.08 B. Fungal Infections

- Add “7. Blastomycosis”
- Add “8. *Pencillium marnefei*”

14.08 C Protozoan or helminthic infections

- Add “5. Leishmaniasis”
- Add “6. Microsporidiosis”

14.08 I. Wasting Syndrome

The guidelines for diagnosing wasting syndrome should be modified to reflect advances in medical knowledge regarding this condition.^{11 12} Specifically, we recommend changing this bullet to the following:

- HIV wasting syndrome, characterized by involuntary weight loss of 5 percent or more below ideal body weight and, in the absence of a concurrent illness that could explain the findings, constitutional symptoms.

Add Chronic Pancreatitis (as 14.08 M) to the Stand-Alone Listing

Finally, we strongly recommend adding chronic pancreatitis to the stand-alone listings. This condition occurs at a higher rate among people with HIV disease and severely impairs an individual’s ability to function.¹³

14.08 N. Repeated Manifestations

As referred to in previous sections, the treatments now available for HIV disease are lifesaving but disabling in their own right. We recommend modifying the repeated manifestations section to reflect the diversity of disabling conditions that result from HIV disease or its therapies. Specifically, we propose adding the following language to the text of N:

¹¹ Tang AM, et al. Weight Loss and Survival in HIV-positive Patients in the Era of Highly Active Antiretroviral Therapy. *J Acquir Immune Defic Syndr* 2002; 31(2): 230-6.

¹² Wheeler DA. Weight Loss and Disease Progression in HIV Infection. *AIDS Read.* 1999; 9(5) 347-53.

¹³ Gan I, et al. Pancreatitis in HIV Infection: Predictors of Severity. *Am J Gastroenterol* 2003;98(6): 1278-83.

- “Special consideration should be given to other conditions, signs and symptoms deemed by the primary care provider as contributing to substantial functional limitations.”
- Other manifestations that occur frequently among people with HIV and that should be provided as examples in this section for medical examiners are persistent fatigue, nausea, pain, fevers, and mental disorders.

114.03. Documentation of HIV infection in children

The definition of HIV infection in children should be updated to reflect current knowledge and to make it more simple. The definitions are provided, and periodically updated, in the consensus guidelines from the Working Group on Pediatric HIV Infection (available at <http://www.aidsinfo.nih.gov/guidelines/>). In children less than 12 months of age, HIV infection is documented by demonstration of virus by either HIV DNA PCR, HIV RNA PCR or culture, with confirmation by repeat testing. For children older than 18 months, HIV is diagnosed by the presence of HIV antibody on EIA and confirmed by Western Blot. HIV infection should not be currently diagnosed by the presence of antibody with changes in CD4 counts as described in section b. This should not invalidate the diagnosis in past years, but should not be used for new diagnoses.

Objective criteria exist for assessing developmental delay and should be incorporated into the definition of specific conditions. These include neurodevelopmental testing and formal assessment by clinicians trained in development.

114.07 Effect of treatment

As was mentioned above, treatment may cause side effects in children, as in adults, that are disabling by themselves or exacerbate the symptoms of disease. Similar considerations should be made for children, as discussed above.

Please do not hesitate to contact us if you have questions about these comments or require additional medical expertise as you move forward in this process.

Respectfully submitted by,



Christine Lubinski
Executive Director
HIV Medicine Association